DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

ROCHE DIAGNOSTICS CORPORATION
NATHAN CARRINGTON
DIRECTOR OF REGULATORY AFFAIRS
9115 HAGUE ROAD
INDIANAPOLIS IN 46250

December 17, 2014

Re: K142089
Trade/Device Name: ACCU-CHEK Aviva Expert Blood Glucose Monitoring system
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: LFR, NDC
Dated: November 07, 2014
Received: November 12, 2014

Dear Dr. Nathan Carrington:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k142089

Device Name
ACCU-CHEK Aviva Expert

Indications for Use *(Describe)*
The ACCU-CHEK Aviva Expert System is indicated as an aid in the treatment of insulin-requiring diabetes. The ACCU-CHEK Aviva Expert System consists of the ACCU-CHEK Aviva Expert Meter, ACCU-CHEK Aviva Plus test strips, ACCU-CHEK Aviva control solutions, and ACCU-CHEK Bolus Advisor. The ACCU-CHEK Aviva Expert System is intended to facilitate the optimization of glycemic control in patients who are trained in multiple daily insulin injection therapy and are under the supervision of healthcare professionals experienced in managing insulin treated patients.
The ACCU-CHEK Aviva Expert blood glucose monitoring system is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The ACCU-CHEK Aviva Expert blood glucose monitoring system is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes. The ACCU-CHEK Aviva Expert blood glucose monitoring system is intended to be used by a single person and should not be shared. The ACCU-CHEK Aviva Expert blood glucose monitoring system should not be used for the diagnosis or screening of diabetes or for neonatal use. Alternative site testing should NOT be used with the ACCU-CHEK Aviva Expert blood glucose monitoring system. The ACCU-CHEK Aviva Expert System is intended for prescription home use only.
The ACCU-CHEK Aviva Expert meter is also indicated for the calculation of an insulin dose or carbohydrate intake based on user-entered data. The ACCU-CHEK Bolus Advisor, as a component of the Accu-Chek Aviva Expert meter, is intended for use in providing insulin dose recommendations in response to blood glucose, health events, and carbohydrate input. The ACCU-CHEK Bolus Advisor is intended to provide direction for insulin adjustment within the scope of a pre-planned treatment program from a healthcare professional. Before its use, a physician or healthcare professional must prescribe the ACCU-CHEK Aviva Expert System and provide the patient-specific target blood glucose, insulin-to-carbohydrate ratio, and insulin sensitivity parameters to be programmed into the ACCU-CHEK Bolus Advisor. Once programmed, a patient must consult with his/her physician or healthcare professional before making any changes to these ACCU-CHEK Bolus Advisor settings.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
Contact Person: Nate Carrington
Ph: (317) 521-4793
email: nate.carrington@roche.com
Date Prepared: December 10, 2014

2) Device name

Proprietary names:

ACCU-CHEK® Aviva Expert Blood Glucose Monitoring System

Classification names:

Glucose Dehydrogenase, Glucose (21 CFR 862.1345);
Class II; Product Code: LFR

Drug dosing calculator (21 CFR 868.1890);
Class II; Product Code: NDC

3) Predicate device

The predicate device for this submission is the ACCU-CHEK® Aviva Expert Blood Glucose Monitoring system, cleared in #k131366.

Predicate Device Intended Use Statement:

The ACCU-CHEK Aviva Expert System is indicated as an aid in the treatment of insulin-requiring diabetes. The ACCU-CHEK Aviva Expert System consists of the ACCU-CHEK Aviva Expert Meter, ACCU-CHEK Aviva Plus test strips, ACCU-CHEK Aviva control solutions, and ACCU-CHEK Bolus Advisor. The ACCU-CHEK Aviva Expert System is intended to facilitate the optimization of glycemic control in patients who are trained in multiple daily insulin injection therapy and are under the supervision of healthcare professionals experienced in managing insulin treated patients.

The ACCU-CHEK Aviva Expert blood glucose monitoring system is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The ACCU-CHEK Aviva Expert blood glucose monitoring system is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes. The ACCU-CHEK Aviva Expert blood glucose monitoring system is intended to be used by a single person and should not be shared. The ACCU-CHEK Aviva Expert blood glucose monitoring system should not be used for the diagnosis or screening of diabetes or for neonatal use. Alternative site testing should NOT be used with the ACCU-CHEK Aviva Expert blood glucose monitoring system. The ACCU-CHEK Aviva Expert System is intended for prescription home use only.

The ACCU-CHEK Aviva Expert meter is also indicated for the calculation of an insulin dose or carbohydrate intake based on user-entered data. The ACCU-CHEK Bolus Advisor, as a component of the Accu-Chek Aviva Expert meter, is intended for use in providing insulin dose recommendations in response to blood glucose, health events, and carbohydrate input. The ACCU-CHEK Bolus Advisor is intended to provide direction for insulin adjustment within the scope of a pre-planned treatment program from a healthcare professional. Before its use, a physician or healthcare professional must prescribe the ACCU-CHEK Aviva Expert System and provide the patient-specific target blood glucose, insulin-to-carbohydrate ratio, and insulin sensitivity parameters to be programmed into the ACCU-CHEK Bolus Advisor. Once programmed, a patient must consult with his/her physician or healthcare professional before making any changes to these ACCU-CHEK Bolus Advisor settings.

4) Device Description

The ACCU-CHEK Aviva Expert System consists of the following which was originally cleared under k131366:

- ACCU-CHEK Aviva Expert meter
- ACCU-CHEK Bolus Advisor (a component of the Aviva Expert meter)
- ACCU-CHEK Aviva Plus test strips
- ACCU-CHEK Aviva control solutions

The ACCU-CHEK Aviva Expert system is a blood glucose monitoring system that makes use of the ACCU-CHEK Aviva Plus test strips and the ACCU-CHEK Aviva control solutions.

The ACCU-CHEK Aviva Expert system provides the user with the ability to measure capillary blood glucose levels when a sample of capillary blood is applied to the test strip. The meter also provides an optional insulin bolus calculator (the ACCU-CHEK Bolus Advisor) designed for use by individuals with diabetes who require insulin. This feature is optional in that a user can simply obtain a blood glucose value through capillary blood testing and does not need to use the insulin bolus calculator portion of the system if it is not desired. For the ACCU-CHEK Aviva Expert system, this bolus calculator is meant to be used by patients with diabetes on multiple daily insulin injection (MDI) therapy. In order to calculate the appropriate bolus of insulin, the ACCU-CHEK Bolus Advisor takes the measured bG, the target bG, the carbohydrate intake, the insulin-to-carbohydrate ratio, the insulin sensitivity, health events (such as exercise), the time of day, and the active insulin into account. Before using the ACCU-CHEK Aviva Expert system, a physician or healthcare professional must provide the patient-specific target blood glucose, insulin-to-carbohydrate ration, and insulin sensitivity parameters.

Continued on next page

510(k) Summary, Continued

5) Intended use

The ACCU-CHEK Aviva Expert System is indicated as an aid in the treatment of insulin-requiring diabetes. The ACCU-CHEK Aviva Expert System consists of the ACCU-CHEK Aviva Expert Meter, ACCU-CHEK Aviva Plus test strips, ACCU-CHEK Aviva control solutions, and ACCU-CHEK Bolus Advisor. The ACCU-CHEK Aviva Expert System is intended to facilitate the optimization of glycemic control in patients who are trained in multiple daily insulin injection therapy and are under the supervision of healthcare professionals experienced in managing insulin treated patients.

The ACCU-CHEK Aviva Expert blood glucose monitoring system is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The ACCU-CHEK Aviva Expert blood glucose monitoring system is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes. The ACCU-CHEK Aviva Expert blood glucose monitoring system is intended to be used by a single person and should not be shared. The ACCU-CHEK Aviva Expert blood glucose monitoring system should not be used for the diagnosis or screening of diabetes or for neonatal use. Alternative site testing should NOT be used with the ACCU-CHEK Aviva Expert blood glucose monitoring system. The ACCU-CHEK Aviva Expert System is intended for prescription home use only.

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6) Substantial equivalence

The ACCU-CHEK® Aviva Expert System is substantially equivalent to the ACCU-CHEK® Aviva Expert System.

7) Data demonstrating substantial equivalence

Performance testing on the ACCU-CHEK® Aviva Expert System that demonstrates that the device meets the performance requirements for its intended use was submitted and cleared under k131366. The ACCU-CHEK® Aviva Expert System has not changed since this prior submission and the information submitted here is provided to support the clarification in the intended use statement. A data summary is provided below for convenience.

Similarities table comparing the subject device to the predicate device

System Feature/Claim	Detail
Test Strip	**Identical**: Both systems make use of the Aviva Plus test strip.
Test Strip Production Processes and Lot-Release Criteria	**Identical**: Both systems make use of the Aviva Plus test strip.
bG Measurement Algorithm	**Identical**: The fundamental scientific technology for the measurement of blood glucose has not changed from the predicate.
Meter Main Integrated Circuit Board	**Identical**: The firmware components and layout are identical between the two meters.
Meter Display Module, Display Frame, and Button Module	**Identical**: The same display unit, display frame, and button unit are used by the two meters.
Meter Housing and Battery Contacts	**Identical**: For both meters, the plastic parts are produced by the same molding tool using the same material, and the battery contacts are the same.
Meter Production Environment	**Identical**: Both meters are produced on one production line/process.

Underdose Detection and Meter Failsafes	**Identical**: The fundamental scientific technology for the measurement of blood glucose has not changed from the predicate.
Integrity Check for Strip	**Identical**: Early in the measurement sequence, the meter measures the resistance of the gold on the un-dosed strip to assure that it has been properly inserted and that the quality is not compromised. The meter measures the background conductivity and electrical current prior to dosing to assure that the reagent quality is not compromised or that the strip was not prematurely dosed.
Insulin Bolus Calculator Algorithm	**Identical:** Both systems use the exact same bolus calculator, the ACCU-CHEK Bolus Advisor, for insulin dosing calculations.
Test Principle	**Identical:** Amperometric Detection
Enzyme	**Identical:** Mut. Q-GDH
Sample Hematocrit	**Identical:** 10 to 65%
Maximum Altitude	**Identical:** 10,000 feet
Measuring Range	**Identical:** 20 – 600 mg/dL
Sample Volume	**Identical:** 0.6 µL
Test Time	**Identical:** 5 seconds
Operating Temperature and Relative Humidity	**Identical:** 14 to 38ºC (57 to 100ºF) 10 to 80% r.h.
Coding	**Identical:** Code key insertion
Precision	**Identical:** For response targets below 75 mg/dL, the SD is ≤ 5.0 mg/dL, and for response targets ≥ 75 mg/dL, the CV is ≤ 5.0%.
Double Dosing	**Identical:** Not allowed
Alternate Site Testing	**Identical:** Not allowed
Closed and Open Vial Shelf Life Stability	**Identical:** 18 months
Control Solutions	**Identical:** Aqueous, 2 levels, uses ACCU-CHEK Aviva Control Solutions

Primary Packaging	**Identical:** Standard flip top vial
Handling	**Identical:** Automatic on/off with strip insertion or by pressing button
Dimensions	**Identical:** 3.7 x 2.1 x 1 in LWH; approximately 3.6 oz. with batteries inserted
Data Transfer	**Identical:** Infrared
Date Reminders	**Identical**
bG Test Reminders	**Identical**
Alarm Clock Reminders	**Identical**
Target bG Levels	**Identical**
Health Events	**Identical**
Electronic Diary	**Identical**
Limitations of Procedure	**Identical:** Galactose >15 mg/dL will cause overestimation of blood glucose results.
	Identical: Lipemic Samples >1800 mg/dL
	Identical: Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid >3 mg/dL will cause overestimation of blood glucose results
RF Wireless Capability	**Identical:** No
Measurement Units of Insulin Bolus Result Calculations	**Identical:** 0.5 units (appropriate for syringe/pen administration of insulin)
Basal Insulin*	**Identical:** Diary feature for tracking basal insulin
User Group	**Identical:** Diabetes patients treated with multiple daily insulin injection (MDI) therapy

* The basal insulin values that are recorded do not influence the bolus advice.

Data demonstrating substantial equivalence

Performance testing on the ACCU-CHEK Aviva Expert System demonstrated that the device meets the performance requirements for its intended use.

Below is the method comparison data for the system:

Results for glucose concentrations less than 75 mg/dL

Within ±5 mg/dL	Within ±10 mg/dL	Within ± 15 mg/dL
41/48 (85.4%)	48/48 (100%)	48/48 (100%)

Results for glucose concentrations greater than or equal to 75 mg/dL

Within ±5 %	Within ±10 %	Within ± 15 %	Within ± 20 %
147/252 (58.3%)	222/252 (88.1%)	246/252 (97.6%)	250/252 (99.2%)

Below is the repeatability (wtihin lot) precision for the system:

Blood	**1**	**2**	**3**	**4**	**5**
N	100	100	100	100	100
Mean [mg/dL]	42.1	84.5	137.8	208.2	345.0
SD [mg/dL]	1.2	2.2	3.3	5.6	7.9
CV [%]	2.9	2.6	2.4	2.7	2.3

Below is the reproducibility (intermediate or day-to-day) precision for the system:

Control solutions	**Low**	**Mid**	**High**
N	100	100	100
Mean [mg/dL]	45.1	117.6	303.0
SD [mg/dL]	1.1	2.4	5.1
CV [%]	2.4	2.0	1.7

Differences:

The only difference between the two devices is updated information in the meter manuals relating to recent clinical studies involving bolus calculators.

The Aviva Expert Standard Owner's Manual, Advanced Owner's Manual, and Getting Started Guide have all been updated with the following information:

Important Information About Bolus Calculators

- The ACCU-CHEK Aviva Expert System contains the ACCU-CHEK Bolus Advisor, a bolus calculator that is intended for use in providing insulin dose recommendations in response to blood glucose, health events, and carbohydrate input.

- Bolus calculators, such as the ACCU-CHEK Bolus Advisor, have been demonstrated to facilitate the optimization of glycemic control in patients who are trained in multiple daily insulin injection therapy and under the supervision of healthcare professionals experienced in managing insulin-treated patients.[1] Such calculators have also been shown to reduce patient fear of hypoglycemia and improve patient confidence in diabetes management.[2]

1. R Ziegler et al.: Use of an insulin bolus advisor improves glycemic control in multiple daily insulin injection (MDI) therapy patients with suboptimal glycemic control: first results from the ABACUS trial; *Diabetes Care* 36, 3613-3619 (2013).

2. K Barnard et al.: Use of an automated bolus calculator reduces fear of hypoglycemia and improves confidence in dosage accuracy in patients with type 1 diabetes mellitus treated with multiple daily insulin injections; *J. Diabetes Sci. Technol.* 6:1, 144-149 (2012).